

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: C. R. BARD PELVIC REPAIR)	
SYSTEM PRODUCTS LIABILITY)	
LITIGATION)	Master File No. 2:10-md-02187
)	MDL No. 2187
<hr/>		
THIS DOCUMENT RELATES TO:)	
)	
<i>Eunice Arruda</i>)	JOSEPH R. GOODWIN
<i>v.</i>)	U.S. DISTRICT JUDGE
<i>C.R. Bard, Inc.</i>)	
Case No. 2:12-cv-8880)	

**PLAINTIFF’S MEMORANDUM OF LAW IN SUPPORT OF HER MOTION TO
EXCLUDE THE OPINIONS OF STEPHANIE MOLDEN, M.D., FACOG**

Plaintiff, Eunice Arruda, pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), submits this Memorandum of Law in Support of Motion to Exclude the Opinions of defense expert witness, Stephanie Molden, M.D., FACOG. In support thereof, Plaintiff respectfully submits the following:

INTRODUCTION

Dr. Molden is a urogynecologist designated by C.R. Bard, Inc. (“Bard”) as a general causation expert. Plaintiffs previously set forth a motion to exclude Dr. Molden’s general causation opinions. Plaintiffs incorporate herein by reference the prior Daubert Motion and Reply Brief regarding Dr. Molden’s testimony. *See* Notice of Adoption of Prior Daubert Mot. of Stephanie Molden, M.D., F.A.O.G. for Wave 8, Wave 9 and Wave 10 Cases [MDL No. 2187, ECF No. 7260].

Bard has also retained Dr. Molden to opine about specific causation with regard to Eunice Arruda. On December 4, 2008, Dr. James Pfeiff implanted an Align TO in Ms. Arruda to surgically correct stress urinary incontinence. Ms. Arruda suffered personal injuries as a result of the

implantation, including undergoing a procedure to remove in part the Align TO. Bard's expert witness, Dr. Molden, disagrees. A copy of Dr. Molden's report is attached hereto as Exhibit A. For the reasons set forth below, the Court should exclude the opinions of Dr. Molden.

LEGAL STANDARD

"Scientific testimony is relevant only if the expert's reasoning or methodology can be properly applied to the facts in issue, meaning that there is an appropriate fit between the scientific testimony and the specific facts of the case." *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 593 (1993). Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to scientific knowledge that will assist the trier of fact to understand or determine a fact in issue. *Id.* "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.*

If the court determines that the proffered expert testimony that has a greater potential to mislead than to enlighten, the testimony should be excluded. *See Hines v. Wyeth*, C.A. No.2:04-0690, 2011 WL 2792436, *2 (S.D. W. Va. July 14, 2011). In fact, this Court has recognized in the Pelvic Repair Product Liability Litigation:

Just because an expert may be "qualified . . . by knowledge, skill, experience, training or education" does not necessarily mean that the opinion that the expert offers is "the product of reliable principles and methods" or that the expert "has reliably applied the principles and methods to the facts of the case."

Cisson v. C.R. Bard, Inc., 2013 U.S. Dist. LEXIS 78061, * 42-43 (S.D.W.V. 2013).

The court's focus in a *Daubert* inquiry should be solely on the experts' "principles and methodology, not on the conclusions that they generate" *Maryland Cas. Co. v. Therm-O-Disc*,

Inc., 137 F.3d 780, 783 (4th Cir. 1998) because “Daubert governs whether evidence is admitted, not how persuasive it must be to the factfinder.” *Cavallo*, 100 F.3d at 1158.

The focus on “principles and methodology” provides additional guidance on factors to be considered when examining the “reliability” of expert testimony. Expert evidence based on assumptions unsupported by the record should be excluded. *Tyger Const. Co. v. Pensacola Const. Co.*, 29 F.3d 137, 144 (4th Cir. 1994) (district court abused its discretion by admitting expert testimony due to the absence of factual support and the speculative nature of the underlying calculations); *see also Brumley v. Pfizer, Inc.*, 200 F.R.D. 596, 600 (S.D. Tex. 2001); Fed. R. Evid. 702. The expert opinion must be based on knowledge and not belief or speculation. *See Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) (“an expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation”). The Fourth Circuit has recognized that “when the assumptions made by an expert are not based on fact, the expert's testimony is likely to mislead a jury, and should be excluded by the district court.” *Tyger Const. Co.*, 29 F.3d at 144.

Courts should further examine whether the expert has properly considered and accounted for facts that undermine or call into question the foundation for the opinion. This Court has excluded expert testimony where the opinion failed to account for other possible causes of injuries. *In re Digitek Products Liab. Litig.*, 821 F. Supp. 2d 822, 841 (S.D. W. Va. 2011) (excluding expert opinion that did not adequately account for other possible causes of injuries); *Payne v. Wyeth Pharms., Inc.*, No. 2:08cv119, 2008 U.S. Dist. LEXIS 106771, *15 (E.D. Va. Nov. 14, 2008).

Moreover, expert opinion must be based on concrete facts and not merely the expert’s own subjective observations and beliefs. The United States Supreme Court, the Fourth Circuit and this Court have all expressly held that an opinion based on nothing more than the *ipse dixit* of the expert

is inadmissible. *See, e.g., General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) (holding that “nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit [an assertion made but not proved] of the expert”); *Cooper*, 259 F.3d at 202-03 (same); *Bourne v. E.I. Dupont de Nemours & Co., Inc.*, 189 F. Supp. 2d 482, 499 (S.D. W. Va. 2002) (same); *see also Hoffman v. Monsanto Co.*, No. 2:05-CV- 00418, 2007 WL 2984692, *4 (S.D. W. Va. Oct. 11, 2007) (excluding an opinion that was based on “simply a subjective, conclusory approach that cannot reasonably be assessed for reliability”) (quoting Fed. R. Evid. 702, advisory committee’s note (2000)). “A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods.” *Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4th Cir.1999).

The Supreme Court has warned: expert testimony can be “both powerful and quite misleading.” *Daubert*, 509 U.S. at 595. Where, as here, the proponent fails to establish all of the prerequisites, the exclusion of expert testimony is within the trial court’s sound discretion. *See General Electric Co.*, 522 U.S. at 142; *see also Cooper*, 259 F.3d at 200.

ARGUMENT

I. Dr. Molden’s general causation opinions on the FDA should be excluded because they are unreliable.

Should the Court find Dr. Molden qualified to opine on general opinions, her opinions based on her reliance on the FDA should be excluded. Dr. Molden states that she relies “on the FDA standards to guide the decisions of safety for human use.” Ex. A at 14. However, she testified that she disagrees with the FDA’s April 16, 2019 decision to halt the sale of mesh products for the treatment of pelvic organ prolapse. Ex. B 31:10-13. She finds fault with the FDA’s decision because “they’re not the ones using it and seeing it and treating patients every day.” Ex. B at 30:6-

9. Interestingly, Dr. Molden is unconcerned with the FDA's lack of clinical experience when she agrees with its opinions, such as its current position on mesh slings. Dr. Molden cherry-picks FDA opinions, using the FDA when it supports her agenda, but completely discounting it when she disagrees with it. This evidences Dr. Molden's flawed methodology, calling into question the foundations for her opinions and undermining her credibility as an expert witness.

II. Dr. Molden's specific causation opinions should be excluded because they are unreliable.

Because Dr. Molden's general causation testimony is inadmissible, the Court should exclude her specific causation testimony for this reason alone. *In re C.R. Bard Inc.*, 948 F.Supp.2d 589, 605 (S.D.W.V. June 4, 2013) (finding that because expert's general causation opinions are not based on reliable methodology and principles, her specific causation opinions must be excluded as well) (internal citations omitted). Additionally, Dr. Molden's specific causation opinions should be excluded in their entirety for the following reasons.

A. Dr. Molden's opinions should be excluded because they lack any reliable methodology or principles.

Dr. Molden fails to provide perform a reliable differential diagnosis. This Court has recognized that a reliable "differential diagnosis" passes *Daubert* muster:

Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.

Cisson, et al. v. C. R. Bard, Inc., 2:11-cv-00195, 2013 U.S. Dist. LEXIS 78061 at *12 (S.D.W.Va. June 4, 2013) (quoting *Westberry*, 178 F.3d at 262 (4th Cir. 1999)). The Court has provided further guidance as to what constitutes a reliable differential diagnosis:

[A differential diagnosis] generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. at *12-13 (quoting *Westberry*, 178 F.3d at 262) (emphasis supplied). *See also Hines v. Wyeth*, No. 2:04-0690, 2011 U.S. Dist. LEXIS 76522, *12 (S.D.W.Va. July 14, 2011); *In re: Digitek Prod. Liab. Litig.*, 821 F. Supp. 2d 822, 837-38 (S.D.W.Va. 2011). Further, an unreliable differential diagnosis is one that “fails to take serious account of other potential causes,” and the expert can offer “no explanation why [he] has concluded [an alternative cause offered by the opposing party] was not the sole cause.” *Id.* at *13

In her report, Dr. Molden states, “to a reasonable degree of medical probability and certainty, Ms. Arruda’s complaints are not likely caused by the Bard Align product...” Ex. A at 19. But when asked to describe her differential diagnosis, Dr. Molden reveals a faulty methodology that does not qualify as a differential diagnosis at all. Rather than eliminating alternative causes until reaching one that cannot be ruled out, Dr. Molden testified to a number of alternate causes and said none can be ruled out, including the Align TO, and also failed to state with any degree of medical certainty which, if any, of the alternative causes is actually causing Plaintiff’s complaints.

For example:

- Q. Did you rule out the Align TO as a cause of Ms. Arruda's pelvic pain in this case?
A. I did not rule it out.
Q. In your opinion, is the Align TO a possible cause of Ms. Arruda's pelvic pain in this case?
A. I think it is a possible cause of some of her pelvic pain, but not all. Ex. B at 63:12-19.
- Q. Did you rule out the Align TO as a cause of the painful sex that Ms. Arruda was experiencing?
A. I did not rule it out completely; no.
Q. And, again, you list several things that you believe could possibly be the reason that she was experiencing painful sex. Is that correct?
A. It could be the reason or in addition to; yes. *Id.* at 68:23-69:9 (defense counsel’s objections omitted).
- Q. Did you rule out Ms. Arruda's continued urge incontinence as being caused by the Align -- implantation of the Align TO sling?

- A. I did not rule it out.
- Q. Why not?
- A. Because, as we just mentioned, it is a possible risk factor for increasing those symptoms in some patients. *Id.* at 96:17-24.
- Q. So, again, here you're saying it's a possibility that this is -- you're using that for possibility; is that correct?
- A. I cannot rule out the fact that she had preoperative voiding dysfunction issues based on her history.
- Q. But you're not saying that to a reasonable degree of medical certainty she had those issues?
- A. She definitely had those issues at one point. We don't know if they resolved prior to the sling, because there's no documentation to support that. *Id.* at 58:8-20.

In her report, Dr. Molden fails to state with any degree of medical certainty that any one cause, or multiple causes, proximately caused Plaintiff's complaints. Regarding Ms. Arruda's pain, Dr. Molden states, "Her pain is so diffuse, and she has so many reasons for the pain that it is nearly impossible to attribute the pain to any one cause..." Ex. A at 17.

Further, Dr. Molden offers speculative opinions. Expert evidence based on assumptions not supported by the record should be excluded. *Tyger Const. Co. v. Pensacola Const. Co.* at 144. For example, Dr. Molden states in her report:

Unfortunately, no direct examination findings were documented of her other pelvic floor muscles directly, but it is likely that other muscles associated with the levator ani complex of musculature also display such findings and likely tenderness on examination, which may be part of her pelvic pain and dyspareunia complaints.

Ex. A at 17-18. When questioned the reason for Ms. Arruda's dyspareunia, Dr. Molden states, "Honestly, she has a poor exam and evaluation of her pain in her records. I don't think it was fully vetted." Ex. B at 72:17-73:3. Dr. Molden did not see what she wanted in the records, so she assumes Ms. Arruda was not thoroughly examined. Even more examples of speculation include Dr. Molden's opinion that Ms. Arruda's risk of neurogenic bladder is "especially likely" and it is "very possible that Ms. Arruda has neuropathy affecting her bladder." Ex. A at 18. Such testimony is not scientifically valid and is likely to mislead a jury.

Because Dr. Molden rules in a variety of alternative causes while eliminating none, and bases her opinions on unsupported assumptions, her opinions do not amount to a case-specific causation opinions, but rather, a lack of causation opinions. As this Court has previously held, such opinions are “not helpful to the jury because [they are] not made to a reasonable degree of medical certainty.” *Huskey v. Ethicon, Inc.*, Case 2:12-cv-05201, Dkt. No. 271, p. 52. Therefore, her opinions as to the cause of Ms. Arruda’s injuries should be excluded in their entirety.

CONCLUSION

Based on the foregoing, Dr. Molden’s opinions should be excluded because her opinions are wholly unreliable. Her methodology is flawed because it calls into question the foundations for her opinions and undermines her credibility. Further, her opinions are devoid of a reliable differential diagnosis. Such testimony would fail to assist the trier of fact in understanding the evidence, determining facts in issue, and poses a greater potential to mislead than to enlighten. For these reasons, and those set forth hereinabove, Dr. Molden should be precluded from offering general and case specific testimony.

Dated: May 13, 2019

Respectfully submitted,

s/ Merritt E. Cunningham
Michael G. Stag, LSBA No. 23314
Merritt E. Cunningham, LSBA No. 32843
STAG LIUZZA, L.L.C.
365 Canal Street, Suite 2850
New Orleans, Louisiana 70130
(504) 593-9600 Telephone
(504) 593-9601 Facsimile
mstag@stagliuzza.com
mcunningham@stagliuzza.com

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of May, 2019, I electronically filed the foregoing Certificate of Service with the Clerk of Court using the CM/ECF system which will send notification of such filing to all attorneys of record.

s/ Merritt E. Cunningham
Merritt E. Cunningham